IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

PUREWICK CORPORATION,)
Plaintiff,)
v.) C.A. No. 22-102-MN
SAGE PRODUCTS, LLC,)
Defendant.)

MEMORANDUM OPINION

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Maryellen Noreika NOREJKA, U.S. DISTRICT JUDGE

Presently before the Court is the motion of Plaintiff PureWick Corporation ("Plaintiff" or "PureWick") for judgment on Defendant's defenses of invalidity and unenforceability under Federal Rule of Civil Procedure 12(c) based on collateral estoppel. (D.I. 12). For the reasons set forth below, Plaintiff's motion is GRANTED-IN-PART and DENIED-IN-PART.

I. BACKGROUND

Plaintiff and Defendant Sage Products, LLC ("Defendant" or "Sage") both sell products related to external vacuum-assisted urine collection. (See D.I. 1 ¶¶ 8-13). More specifically, Plaintiff sells the PureWick FEC Solution, a female external catheter, and Defendant also sells a line of external female catheters, which are marketed under the PrimaFit name. (See id.). The external urine collection devices at issue help reduce the need for indwelling catheters and reduce the incidence of catheter-associated urinary tract infections and other moisture-related skin injuries in women. (See id. ¶ 8). Plaintiff owns several patents related to external female catheters, two of which are relevant to the present motion: U.S. Patent Nos. 10,226,376 ("the '376 Patent") and 10,390,989 ("the '989 Patent"). (See id. ¶¶ 9-10).

On August 12, 2019, Plaintiff sued Defendant for patent infringement, alleging that Defendant's original PrimaFit product ("PrimaFit 1.0") infringed the '376 and '989 Patents.¹ (See generally PureWick Corp. v. Sage Products, LLC, C.A. No. 19-1508-MN ("PureWick I"); see also PureWick I, D.I. 44). In PureWick I, Plaintiff asserted claims 1, 5 and 9 of the '376 Patent and claims 1 and 6 of the '989 Patent. Defendant filed an Answer with defenses and counterclaims of invalidity and unenforceability. (PureWick I, D.I. 53). From March 28, 2022 to April 1, 2022, the Court presided over a jury trial. (See PureWick I, D.I. 326, 327, 328, 329, 330). The jury found

Plaintiff later added two other patents not relevant to the present motion: U.S. Patent Nos. 8,287,508 and 10,376,407. (*See* D.I. 11 & 46).

that Defendant infringed claims 1, 5 and 9 of the '376 Patent and claims 1 and 6 of the '989 Patent and, further, that that infringement was willful. (*See PureWick I*, D.I. 316 at 2-3). The jury also found that Defendant failed to prove that any of the asserted claims is invalid. (*See id.* at 4). The jury awarded Plaintiff \$26,215,545 in lost profits for sales of the PrimaFit 1.0 product. (*Id.* at 5). On April 7, 2022, the Court entered judgment on the jury verdict under Rule 58(b) of the Federal Rules of Civil Procedure. (*PureWick I*, D.I. 320). Post-trial motions ensued.

After dispositive motions but before trial in *PureWick I*, on January 26, 2022, Plaintiff filed the present action against Defendant, alleging that Defendant's PrimaFit 2.0 infringes the '376 and '989 Patents.² (D.I. 1). In this second case, Plaintiff is asserting claims 1, 5, 9 and 10 of the '376 Patent and claims 2-7 of the '989 Patent. (D.I. 75). On May 9, 2022, Defendant filed an Answer to the Complaint, raising a number of defenses, including that the '376 and '989 Patents are invalid and unenforceable. (*See* D.I. 8 ¶ 66-69, 71-84 & 90-115). Thereafter, on June 17, 2022, Plaintiff filed the instant motion under Rule 12(c) seeking judgment on Defendant's defenses of invalidity and unenforceability of the '376 and '989 Patents based on collateral estoppel and res judicata. (D.I. 12). On January 20, 2023, the Court heard oral argument, during which Plaintiff dropped its arguments that these defenses are barred based on res judicata. (*See generally* D.I. 123; *see also id.* at 4:12-20 ("[F]or purposes of this argument and in order to focus down, we're willing to focus down and . . . leave res judicata be for the moment or forever."))).

The Court has just issued its post-trial opinion in *PureWick I*, finding in relevant part that substantial evidence supported the jury's finding of no invalidity of the '376 and '989 Patents and, further, that Plaintiff was entitled to judgment on Defendant's counterclaims of unenforceability and invalidity for which Defendant failed to present evidence on at trial. (*See generally*

² PrimaFit 2.0 was not at issue in the original *PureWick I* trial.

PureWick I, D.I. 368). The issue now before the Court in this second case is whether the determination of no invalidity and no unenforceability in *PureWick I* should apply here under the principles of collateral estoppel.

II. LEGAL STANDARD

Collateral estoppel (also known as issue preclusion) is a doctrine that operates to preclude a party from relitigating an issue that has previously been decided. See Anderson v. Gen. Motors LLC, No. 18-621-LPS, 2019 WL 4393177, at *4 (D. Del. Sept. 13, 2019). Under Third Circuit law, collateral estoppel applies when: (1) the identical issue was previously adjudicated, (2) that issue was actually litigated, (3) the previous determination was necessary to the decision and (4) the party being precluded from relitigating the issue was fully represented in the prior action. See Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc., 458 F.3d 244, 249 (3d Cir. 2006); see also Allergan, Inc. v. Sandoz, Inc., 681 F. App'x 955, 959 (Fed. Cir. 2017) (regional circuit law governs issues of collateral estoppel). The Third Circuit has also described the inquiry as looking to whether the party being precluded had a "full and fair opportunity" to litigate the contested issue in the previous action and whether that issue was decided by a "final and valid judgment." Jean Alexander, 458 F.3d at 249 (citations omitted). Similarly, in the patent context, the Federal Circuit has explained that "a judgment of invalidity will have no collateral estoppel effect if the patentee can show that it did not have a full and fair opportunity to litigate." Pharmacia & Upjohn Co. v. Mylan Pharm., Inc., 170 F.3d 1373, 1379 (Fed. Cir. 1999). "The party seeking to effectuate an estoppel has the burden of demonstrating the propriety of its application." Suppan v. Dadonna, 203 F.3d 228, 233 (3d Cir. 2000).

III. DISCUSSION

The Court begins with a discussion of the invalidity defenses and counterclaims decided in PureWick I before turning to the factors in the collateral-estoppel analysis.

A. <u>Invalidity and Unenforceability Defenses and Counterclaims in PureWick I</u>

In *PureWick I*, Defendant asserted that the patents-in-suit were invalid under § 102, § 103 and/or § 112 and that the patents were unenforceable based on several grounds. (*PureWick I*, D.I. 53 ¶¶ 133 & 135; *see also id.* at Counterclaims II & III)). By the time of trial, the remaining asserted claims were claims 1, 5 and 9 of the '376 Patent and claims 1 and 6 of the '989 Patent.³ (*See PureWick I*, D.I. 286 ¶¶ 33 & 34 & D.I. 303 (adopting pretrial order)). At trial, Defendant presented the following invalidity defenses: anticipation of claims 1, 5 and 9 of the '376 Patent, anticipation of claim 1 of the '989 Patent,⁴ obviousness of claims 1, 5 and 9 of the '376 Patent and obviousness of claims 1 and 6 of the '989 Patent. The jury found that Defendant failed to prove by clear and convincing evidence that any of the asserted claims were invalid as alleged. (*See PureWick* I, D.I. 316). Judgment was entered in favor of Plaintiff and against Defendant on the invalidity of claims 1, 5 and 9 of the '376 Patent for anticipation and obviousness, on the invalidity of claim 1 of the '989 Patent for anticipation and obviousness and on the invalidity of claim 6 of the '989 Patent for obviousness. (*See PureWick I*, D.I. 320 ¶¶ 3 & 4).

Also relevant to the present motion, although Defendant in *PureWick I* pleaded unenforceability defenses and counterclaims of "waiver, estoppel, unclean hands and/or acquiescence," Defendant did not introduce any evidence at trial in *PureWick I* in support of those theories. (*See PureWick I*, D.I. 53 ¶ 135 & Counterclaim II ¶ 53 (unenforceability counterclaim for '376 Patent) & Counterclaim III ¶ 76 (unenforceability counterclaim for '989 Patent)). Just before trial began in *PureWick I*, Defendant informed Plaintiff that it would not pursue the asserted "equitable defenses, including waiver, estoppel, unclean hands and acquiescence in this case with

Two claims also remained from the '407 Patent, which is not asserted here.

Defendant did not pursue anticipation for claim 6 of the '989 Patent at trial.

respect to PureWick's claims on the '376, '407 and '989 Patents." (*PureWick I*, D.I. 302). After trial, Plaintiff sought judgment on Defendant's unenforceability counterclaims, as well as on certain invalidity counterclaims that also were not pursued at trial – *e.g.*, anticipation of claim 6 of the '989 Patent. (*See PureWick I*, D.I. 337 at 29-30). In its post-trial opinion in *PureWick I*, this Court granted judgment in favor of Plaintiff of no invalidity for anticipation for claim 6 of the '989 Patent, ⁵ as well as judgment in favor of Plaintiff on Defendant's unenforceability counterclaims for the asserted claims of the '376 and '989 Patents because Defendant failed to meet its burden on those counterclaims. (*PureWick I*, D.I. 368 at 37-42). The Court also found that substantial evidence supported the jury's finding of no invalidity of the '376 and '989 Patents. (*Id.* at 13-17).

Thus, whether through the jury verdict or the Court's post-trial grant of judgment, PureWick I decided in favor of Plaintiff and against Defendant the issues of anticipation and obviousness of claims 1, 5 and 9 of the '376 Patent and claims 1 and 6 of the '989 Patent, as well as unenforceability based on waiver, estoppel, unclean hands and acquiescence for those patents.

B. <u>Collateral Estoppel</u>

Here, with a few exceptions, Plaintiff has asserted the same claims of the '376 and '989 Patents against Defendant as were asserted in *PureWick I*. In this case, Plaintiff asserts that Defendant's PrimaFit 2.0 product infringes claims 1, 5, 9 and 10 of the '376 Patent and claims 2-7 of the '989 Patent. Thus, the difference between *PureWick I* and this case is that Plaintiff now additionally asserts claim 10 from the '376 Patent and claims 2, 3, 4, 5 and 7 of the '989 Patent. Of the six new claims at issue here, all but one depend from independent claims whose validity

The Court also granted judgment in favor of Plaintiff and against Defendant on its § 112 invalidity counterclaim for claims 1 and 2 of the '407 Patent. (*PureWick I*, D.I. 368 at 40-42).

was addressed in *PureWick I*, and the other claim Plaintiff has agreed to drop.⁶ Plaintiff argues that Defendant is collaterally estopped from arguing that any of the asserted claims here are invalid or unenforceable. (*See generally D.I.* 13 at 5-14).

1. Identity of the Issues Asserted Here and Decided in *PureWick I*

The first step in the collateral-estoppel analysis is to determine whether the issue to be precluded is identical to the issue previously decided. *See Jean Alexander*, 458 F.3d at 249. "Identity of the issue is established by showing that the same general legal rules govern both cases and that the facts of both cases are indistinguishable as measured by those rules." *Suppan v. Dadonna*, 203 F.3d 228, 233 (3d Cir. 2000) (quotation marks and citation omitted). In the context of patent infringement, Federal Circuit law applies in determining whether the "identity of the issue" requirement of collateral estoppel is met. ** Cf. Aspex Eyewear, Inc. v. Marchon Eyewear, Inc., 672 F.3d 1335, 1341 n.1 (Fed. Cir. 2012) (for res judicata, noting that Federal Circuit law applies to "the question of whether a particular claim in a patent case is the same as or separate from another claim [because that question] has special application to patent cases").

The Court must first resolve a threshold issue. In applying collateral estoppel to invalidity decisions, there is some question as to whether invalidity is a single issue or is divided into distinct issues based on the invalidity grounds -e.g., invalidity for obviousness is a different issue than

The only new independent claim is claim 7 of the '989 Patent. To narrow the issues in this case, Plaintiff agreed to dismiss claim 7 of the '989 Patent. (See D.I. 75 at 2; see also D.I. 123 at 3:12-4:11). Therefore, the Court considers claim 7 of the '989 Patent dropped and it is not addressed in the collateral-estoppel analysis.

Ohio Willow Wood Co. v. Alps S., LLC, 735 F.3d 1333, 1342 (Fed. Cir. 2013) ("Our review of a collateral estoppel determination is generally guided by regional circuit precedent, but we apply our own precedent to those aspects of such a determination that involve substantive issues of patent law."); see also Soverain Software, 778 F.3d at 1314 ("We apply this court's precedent to questions involving substantive issues of patent law, issues of issue preclusion that implicate substantive patent law issues, or issues of issue preclusion that implicate the scope of our own previous decisions.").

invalidity for anticipation. See Orexo AB v. Actavis Elizabeth LLC, 371 F. Supp. 3d 175, 183 (D. Del. 2019) (noting the outstanding question, compiling cases addressing the issue and concluding that validity should not be treated as a single issue for collateral estoppel). The parties disagree as to whether identical issues were previously litigated in PureWick I and a substantial part of that disagreement comes from their divergent views on whether invalidity is treated as a single issue. Plaintiff argues that invalidity is a single issue and, as long as Defendant pursued some invalidity issue in PureWick I, it is estopped from asserting any invalidity defense here. (D.I. 13 at 6-7). Defendant, on the other hand, argues that invalidity is not a single issue for purposes of collateral estoppel. (D.I. 19 at 15-16).

Neither the Federal Circuit nor the Third Circuit has addressed the question of whether invalidity is a single issue or is divided into distinct issues based on the invalidity grounds. See Sprint Commc'ns Co. L.P. v. Charter Commc'ns, Inc., No. 17-1734-RGA, 2021 WL 982726, at *5 (D. Del. Mar. 16, 2021). The decisions in this District are split on the issue. (Compare Astrazeneca UK Ltd. v. Watson Lab'ys, Inc. (NV), 905 F. Supp. 2d 596, 602-03 (D. Del. 2012) (concluding that invalidity is a single issue for the purposes of collateral estoppel), with Orexo, 371 F. Supp. 3d at 184 (declining "to adopt a per se rule that validity is a single issue for the purposes of issue preclusion"), and Sprint, 2021 WL 982726, at *6 ("As each theory of invalidity has its own legal rules and seeks a different answer on the question of invalidity, each theory is its own issue for the purposes of issue preclusion."). This Court finds the conclusions and supporting rationales in Orexo and Sprint persuasive.

As explained in *Sprint*, "[t]he Third Circuit instructs that issues are identical where the same general legal rules govern both cases and where the facts of both cases are indistinguishable as measured by those rules." *Sprint*, 2021 WL 982726, at *5 (cleaned up). In the patent context,

each separate invalidity theory is guided by its own legal test and requires different supporting evidence. See Orexo, 371 F. Supp. 3d at 185-86 (discussing the various legal tests to apply for different theories of invalidity). For example, invalidity under § 102 requires proof that a single reference discloses all claim elements as arranged as combined in the claim, whereas invalidity under § 101 for lack of patentable-eligible subject matter requires a showing that the challenged claim(s) are directed to an abstract idea, natural law or natural phenomenon and, further, that the claims also lack an inventive concept sufficient to transform the claim into something more. Compare SynOor, Inc. v. Artesyn Techs., Inc., 709 F.3d 1365, 1375 (Fed. Cir. 2013) (anticipation), with Alice Corp. Ptv. v. CLS Bank Int'l, 573 U.S. 208, 216-17 (2014) (patent eligibility). Consistent with the Federal Circuit's guidance that "it is the identity of the *issues* that were litigated that determines whether collateral estoppel should apply," and because each invalidity theory operates under different legal rules with different supporting evidence, this Court finds that invalidity should not be treated as a single issue. See Ohio Willow Wood, 735 F.3d at 1342. Rather, as in *Orexo* and *Sprint*, this Court finds that each invalidity theory is its own issue for purposes of collateral estoppel. Against this backdrop, the Court now turns to the question of whether the same invalidity issues asserted here were previously decided in *PureWick I*.

a. <u>Anticipation and Obviousness Defenses</u>

PureWick I decided the issue of anticipation and obviousness of claims 1, 5 and 9 of the '376 Patent and claims 1 and 6 of the '989 Patent in favor of Plaintiff and against Defendant. In particular, PureWick I resulted in a judgment that claims 1, 5 and 9 of the '376 Patent and claims 1 and 6 of the '989 Patent are not invalid as anticipated or as obvious. Defendant now asserts that those very same claims, as well as dependent claim 10 from the '376 Patent and dependent claims 2-5 of the '989 Patent, are invalid as anticipated and obvious. (D.I. 8 ¶¶ 66-69). Plaintiff argues that Defendant should be precluded in this case from challenging the asserted claims based on

anticipation and obviousness because the same issue was previously decided in $PureWick\ I$. (D.I. 13 at 6). Even with invalidity not being treated as a single issue, this seems to be a pretty clear-cut application of collateral estoppel – i.e., the no-invalidity findings under § 102 and § 103 from $PureWick\ I$ should operate to preclude Defendant from challenging the same claims and their dependent claims in this case under anticipation or obviousness.⁸

Defendant nevertheless argues that it should not be estopped from pursuing anticipation and obviousness of the '376 and '989 Patents because different prior art is asserted here than in $PureWick\ I$. (D.I. 19 at 17-18). Defendants assert that, because the jury only considered a single prior art reference (Van Den Heuvel), "other prior art issues remain unresolved." (Id. at 17). In Defendant's view, each invalidity theory should be further parsed based on grounds -e.g., anticipation based on Van Den Heuvel is a different issue than anticipation based on Sanchez. ($See\ id$. at 17-18; $see\ also\ D.I.\ 8\ 68$ (listing new prior art for anticipation and obviousness)). The Court declines to adopt such a granular view of invalidity for purposes of collateral estoppel.

As an initial matter, the Court is not persuaded that the cases cited by Defendant require such a result. Although the court in *Orexo* allowed defendant to assert prior art references not decided in the previous litigation, the court explained that "Orexo did not argue, and [the court] therefore d[id] not consider, whether obviousness is a single issue for estoppel purposes." *Orexo*, 371 F. Supp. 3d 175, 187 n.7. Defendant additionally cites to two cases outside this District that

As for the newly asserted dependent claims, Defendant does not dispute that collateral estoppel can apply to dependent claims that were not asserted in the previous action based on findings that the independent claims were not invalid in *PureWick I*. The Court agrees, particularly because a dependent claim cannot be invalid under the same anticipation or obviousness theory that failed to invalidate its independent claim. *See, e.g., Virnetx Inc. v. Apple Inc.*, No. 6:12-855, 2016 WL 1117604, at *3 (E.D. Tex. Mar. 22, 2016) (Defendant collaterally estopped from pursuing anticipation and obviousness of newly asserted dependent claims where, in prior case, Defendant lost on anticipation and obviousness of the independent claims).

found different prior art combinations do not satisfy the requirement that the issues were identical and therefore actually litigated. (D.I. 19 at 17 (citing *Finjan v. Sophos*, 244 F. Supp. 3d 1016, 1031-32 (N.D. Cal. 2017); *Pabst Licensing GmbH v. Samsung Elecs.*, 403 F. Supp. 3d 571, 602-03 (E.D. Tex. 2019))). The Court has reviewed these non-binding cases and remains unpersuaded that, to be eligible for collateral estoppel, a later invalidity defense of anticipation or obviousness must be based on the very same prior art used in the previous decision.

Instead, the Court agrees with the reasoning set forth in *Sprint*, which rejected defendants' argument that the assertion of different prior art than was in the earlier action prevented application of collateral estoppel to defendants' anticipation and obviousness defenses. *Sprint*, 2021 WL 982726, at *9. In finding that mere use of different prior art is not sufficient to destroy identity of the issues, the court offered a helpful example: "for anticipation, the issue is whether there is a piece of prior art with the same limitations as the asserted claim. Whether Prior Art A or Prior Art B is the piece of prior art that meets that requirement is a question of proof, not a different invalidity theory as to why the asserted claim is invalid." *Id.* The court concluded that it would not serve the purposes of collateral estoppel to force Plaintiff to defend against anticipation and obviousness theories previously decided but now based on different prior art. *Id.* The same is true here.

As in *Sprint*, Defendant here simply wants to buttress its previous anticipation and obviousness case with different prior art than was used in *PureWick I*. Because the Court declines to parse anticipation and obviousness further based on individual grounds within each theory, Defendant cannot pursue anticipation or obviousness of the '376 or '989 Patents in this case. The

Defendant cites to *TASER*, in which Judge Andrews explained that "if the invalidity theories are based on . . . different prior art, the requirement of identicality is not satisfied." *TASER Int'l, Inc. v. Karbon Arms, LLC*, 6 F. Supp. 3d 510, 519 (D. Del. 2013). In *Sprint*, however, Judge Andrews walked back that statement, remarking that it "went too far." *Sprint*, 2021 WL 982726, at *9.

issues of anticipation and obviousness of these patents have previously been decided in *PureWick I*. Allowing the assertion of different prior art to destroy the identity of issues for anticipation and obviousness would waste judicial resources and subject parties to the unnecessary expense of multiple litigations. *See Montana v. United States*, 440 U.S. 147, 153-54 (1979) ("To preclude parties from contesting matters that they have had a full and fair opportunity to litigate protects their adversaries from the expense and vexation attending multiple lawsuits, conserves judicial resources, and fosters reliance on judicial action by minimizing the possibility of inconsistent decisions."). Therefore, the Court finds that the issues of anticipation and obviousness previously decided in *PureWick I* are the same issues as Defendant's defenses of invalidity for anticipation and obviousness asserted here.¹⁰

b. Invalidity Defenses Under § 112

Plaintiff argues that Defendant should be precluded from litigating indefiniteness, written description and enablement under 35 U.S.C. § 112 because the same invalidity theories were previously decided in *PureWick I*. (D.I. 13 at 6). This argument largely rests on the Court agreeing that invalidity *in toto* is a single issue, an argument that the Court has rejected. (*See supra* § III.B.1). Therefore, the relevant question is whether the § 112 invalidity issues in *PureWick I* are the same as the § 112 defenses asserted by Defendant here.

In *PureWick I*, Defendant asserted invalidity of the '376 and '989 Patents under indefiniteness, lack of written description and lack of enablement. (*See PureWick I*, D.I. 53 at Counterclaim II ¶ 50 (§ 112 arguments for '376 Patent) & Counterclaim III ¶ 73 (§ 112 theories for '989 Patent); *see also id.* ¶ 133 (affirmative defense of invalidity under § 112 (among others)).

The Court notes that some references included in Defendant's Answer are identical to the references listed in its Answer in *PureWick I.* (*Compare, e.g., PureWick I, D.I.* 53 at Counterclaim II ¶ 46, *with D.I.* 8 ¶ 67).

In this case, Defendant again asserts invalidity of the '376 and '989 Patents under indefiniteness, lack of written description and lack of enablement. (D.I. 8 ¶ 69). Comparing the § 112 theories raised across the two cases leads to the conclusion that the same § 112 invalidity issues asserted here were previously at issue in *PureWick I*. Defendant nevertheless argues that collateral estoppel should not apply here because its § 112 defenses were not presented to the jury and therefore not "previously adjudicated." (D.I. 19 at 13). Moreover, according to Defendant, there are claim constructions in this case that transform their § 112 defenses into a different issue than in *PureWick I*. (*Id.* at 14-15). Defendant did not, however, identify in its briefing any new claim construction theories under § 112. (*Id.*). And when the Court conducted its claim construction in this case, Defendant only identified "fluid reservoir"/"reservoir" as requiring construction, which the Court has construed consistently across both cases. (*See* D.I. 123 at 28:25-29:23). There is no new claim construction in this case that would implicate Defendant's § 112 invalidity defenses.

The first prong of the collateral-estoppel analysis requires more than a finding that the same § 112 theories were at issue in *PureWick I* and this case. The same issue must have been previously decided in *PureWick I*. *See Jean Alexander*, 458 F.3d at 249. This, of course, can be satisfied by entry of final judgment on the issue, but there is no such judgment here. That is not the end of the inquiry, however. *See In re Brown*, 951 F.2d 564, 569 (3d Cir. 1991) ("Unlike claim preclusion, the effectiveness of issue preclusion, sometimes called collateral estoppel, does not require the entry of a judgment, final in the sense of being appealable."). The Third Circuit has adopted a more flexible approach, asking whether an issue is the subject of "prior adjudication . . . in another action that is determined to be sufficiently firm to be accorded conclusive effect." *Henglein v. Colt Indus. Operating Corp.*, 260 F.3d 201, 210 (3d Cir. 2001) (cleaned up). The Court finds that lacking here. Defendant did not present its § 112 theories as applied to the '376 and '989 Patents

at trial in *PureWick I*. Indeed, Defendant did not even include § 112 invalidity as applied to these patents in the Proposed Pretrial Order, despite including § 112 invalidity for the '407 Patent. (*Compare* D.I. 286, Schedule B2 § IV-V (invalidity issues of '376 and '989 Patents remaining for trial limited to anticipation and obviousness), with id. § VI.B (§ 112 invalidity of '407 Patent an issue remaining for trial)). Although Defendant did not formally withdraw its defenses and counterclaims prior to trial, the Court did not at any point in *PureWick I* rule on any § 112 issues as applied to those patents. The Court simply has not been presented with any compelling evidence suggesting that the § 112 issues asserted here are subject to any prior adjudication that should be considered sufficiently firm to give rise to a preclusive effect. Therefore, the Court agrees with Defendant that its indefiniteness, lack of written description and lack of enablement invalidity defenses for the '376 and '989 Patents in this case were not previously decided in *PureWick I*. As such, collateral estoppel does not apply.

c. <u>Unenforceability Defenses</u>

During oral argument, Plaintiff withdrew its argument that Defendant's counterclaims of equitable estoppel, waiver and acquiescence are subject to issue preclusion, so the Court will not address those. (*See* D.I. 123 at 35:24-36:20). The Court considers the only unenforceability issue remaining for this motion to be unclean hands including inequitable conduct. Plaintiff argues that Defendant is collaterally estopped from litigating "unclean hands including inequitable conduct" in this action because the same issue was previously decided in *PureWick I*. (D.I. 13 at 8).

First, as to "unclean hands" without inequitable conduct, the Court has now granted Plaintiff's request for judgment on the unclean-hands defenses and counterclaims for the '376 and '989 Patents. (*PureWick I*, D.I. 368 at 37-40). Therefore, the issue of "unclean hands" has been previously decided in *PureWick I* and Defendant may be collaterally estopped from asserting an unclean hands defense for the '376 and '989 Patents here.

As to inequitable conduct, although Defendant pleaded inequitable conduct for the first time in this case (D.I. 8 ¶ 71-84 & 90-115), Plaintiff nevertheless argues that the factual basis of this defense is the same as the "unclean hands" that was at issue in *PureWick I* (D.I. 13 at 8-9). The Court is unable to determine at this stage whether Defendant's inequitable conduct defense raised in this case should be subject to the collateral estoppel that applies to "unclean hands." This is particularly true because the present motion is one for judgment on the pleadings, and such an inquiry would require the Court to go beyond the pleadings and make factual comparisons between the inequitable conduct defense asserted here and the unclean hands issues previously decided in *PureWick I*. The Court will thus save that issue for another day, deciding only today that Defendant's unclean hands defenses for the '376 and '989 Patents here are the same unclean hands issues that were previously decided in *PureWick I*.¹¹

2. Whether the Invalidity and Unenforceability Issues Were Actually Litigated in *PureWick I*

The next factor in the collateral-estoppel analysis is whether the issue of invalidity was actually litigated in the *PureWick I* action. *See Jean Alexander*, 458 F.3d at 249.

a. <u>Anticipation and Obviousness Defenses</u>

Defendant advances two arguments for why its anticipation and obviousness defenses were not actually litigated in *PureWick I*. (D.I. 19 at 15-19). First, Defendant argues that its anticipation and obviousness defenses were not actually litigated in *PureWick I* because there are new claim construction theories accompanying these defenses in this case. (D.I. 19 at 18-19). In particular, Defendant asserts that Plaintiff in *PureWick I* relied on the position that certain prior art references

Citing no Federal Circuit authority, Plaintiff also summarily argues that Defendant has waived its inequitable conduct defense by failing to assert it as a compulsory counterclaim in *PureWick I*. (D.I. 13 at 13-14). With little authority and barely any argument offered by either side, the Court will not address this issue at this time.

have no "reservoir" but now in this case is arguing that PrimaFit 2.0 has a "reservoir" despite having the same configuration as those prior art references. (Id.). Yet this is Plaintiff's infringement position, and as Plaintiff points out, Defendant did not actually identify any new claim construction theories. (D.I. 21 at 4; see also D.I. 8 ¶ 67). For the first time at oral argument, Defendant asserted that Plaintiff was construing "reservoir" or "fluid reservoir" differently than it had in PureWick I. (D.I. 123 at 10:15-14:2). The Court held an expedited claim construction hearing and construed the term "fluid reservoir" / "reservoir" according to its plain and ordinary meaning, which is "a space where urine can collect." (D.I. 131). In construing the term, the Court also analyzed the record from PureWick I and determined that the construction rendered in this case is consistent with the evidence and arguments made in PureWick I. (Id. at 7). Indeed, the same plain and ordinary meaning of "reservoir" was applied in its post-trial opinion in *PureWick* I. (PureWick I, D.I. 368 at 16 n.12). The plain meaning is thus the same across PureWick I and this case. Given that the meaning of "fluid reservoir" / "reservoir" has been used consistently in PureWick I and here, there is no new claim construction under Defendant's § 102 and § 103 invalidity defenses that bars application of collateral estoppel.

As to the second argument raised by Defendant, the Court has already found that anticipation is a single issue and obviousness is a single issue for purposes of collateral estoppel. (See supra § III.B.1.a). That is, anticipation under one piece of prior art is not a different issue than anticipation under different prior art. The same is true for obviousness and the combinations of prior art used therein. Therefore, the Court has already considered Defendant's argument in the context of "identity of the issues" and declines to revisit it here. The issues of anticipation and obviousness of the '376 and '989 Patents asserted here were litigated in PureWick I.

b. <u>Invalidity Defenses Under § 112</u>

The Court previously found that the § 112 invalidity defenses asserted here were not issues previously decided in *PureWick I.* (*See supra* § III.B.1.b). As such, collateral estoppel cannot apply. For the sake of completeness, however, the Court will address the actual litigation prong of the collateral estoppel analysis.

Defendant argues that its invalidity defenses under § 112 for the '376 and '989 Patents were never presented to the jury and were therefore not actually litigated in *PureWick I*. (D.I. 19 at 13-14). Plaintiff argues that the § 112 defenses and counterclaims were litigated in *PureWick I* as evidenced by invalidity contentions and, despite no jury verdict on those issues, Defendant should not be able to re-litigate them here. (D.I. 21 at 6). "Actual litigation" of an issue within the contours of collateral estoppel does not require the issue be decided by a jury or a formal judgment. *See, e.g., VirnetX Inc. v. Apple Inc.*, 792 F. App'x 796, 803 (Fed. Cir. 2019) ("Apple contends... that it did not 'actually litigate' any invalidity challenge except anticipation by Kiuchi simply because it chose to present to the jury no evidence on any other invalidity issue. We disagree."). Rather, the Court should evaluate the amount of effort spent on that issue through discovery and leading up to trial to determine whether there has been "a true adversarial contest" or something less involved and undeserving of preclusive effect. *Id.* at 805.

Here, there is no indication that Plaintiff spent considerable effort in defending against Defendant's § 112 theories in *PureWick I*. (D.I. 21 at 6 n.5). In fact, although Defendant did not withdraw its § 112 invalidity defenses and counterclaims in advance of trial in *PureWick I*, Plaintiff cites to no expert reports or any other evidence indicating the § 112 issues for the '376 and '989 Patents were the subject of extensive discovery or raised in summary judgment motions. Indeed, there is no mention of § 112 defenses or counterclaims as to the '376 and '989 Patents in the Proposed Pretrial Order. (D.I. 286 ¶ 61; *see also id.* ¶ 62 (mentioning § 112 defense for different

patent)). Under the circumstances here, the Court finds that there was not any sort of "true adversarial contest" over Defendant's § 112 invalidity defenses and counterclaims in *PureWick I* such that they can fairly be considered actually litigated in that case. *See, e.g., Voter Verified, Inc. v. Election Sys. & Software LLC*, 887 F.3d 1376, 1383 (Fed. Cir. 2018) (holding that issue of validity was not "actually litigated" where Defendant did not respond to arguments against invalidity counterclaim). This is further reason to find that collateral estoppel does not apply and that Defendant is not precluded from asserting § 112 invalidity defenses for the '376 and '989 Patents in this case.

c. Unenforceability Defenses

Despite Defendant's arguments to the contrary (D.I. 19 at 9-11), the Court finds that unenforceability based on unclean hands was actually litigated in *PureWick I*. Defendant pleaded unclean hands as an equitable affirmative defense and asserted counterclaims of unenforceability based on unclean hands for both the '376 and '989 Patents, and the parties litigated those issues throughout the course of the *PureWick I* litigation. (*PureWick I*, D.I. 368 at 37-40). Indeed, unenforceability based on unclean hands was included in the Proposed Pretrial Order as a remaining issue for trial. (D.I. 286, Schedule B2 § VII.3 (Defendant's issues of fact that remain to be litigated including "[w]hether Sage can prove by clear and convincing evidence that the '376, '989, and '407 patents are unenforceable due to unclean hands due to the conduct of PureWick')). It was only on the eve of trial in *PureWick I* that Defendant notified Plaintiff that it was no longer pursuing its equitable defenses, including unclean hands. (*See PureWick I*, D.I. 302 ("To further narrow the issues, Sage will not assert its equitable defenses, including waiver, estoppel, unclean hands and acquiescence in this case with respect to PureWick's claims on the '376, '407 and '989 patents.")).

In the Court's view, there was a "true adversarial contest" over the unclean hand defenses and counterclaims as applied to the '376 and '989 Patents, and Plaintiff expended considerable effort "in preparing to meet a case that was never made." *VirnetX*, 792 F. App'x at 804 (cleaned up); *see also id.* (collateral estoppel applied to Apple's invalidity defenses where it previously litigated those issues up to trial, unsuccessfully attempted to dismiss all but anticipation on the eve of trial and was eventually granted judgment as a matter of law for failure of proof). The Court finds it difficult to fathom how what happened here does not qualify as "actual litigation" for purposes of collateral estoppel. *See id.* ("That framing of the issues in the trial-governing pleadings, together with full pretrial engagement on the issues and the eventual judicial rulings resolving the issues based on evidentiary insufficiency, is enough to constitute actual litigation."). Additionally, and perhaps more importantly, the Court has now entered judgment in favor of Plaintiff on unclean hands as applied to the '376 and '989 Patents in *PureWick I*, thereby adding further proof that this issue was "actually litigated" there.

Finally, as to inequitable conduct, the Court defers decision on the issue of whether inequitable conduct as alleged in this case can be subject to the collateral estoppel that applies to unclean hands.

3. Whether the Invalidity and Unenforceability Issues Were Necessary for the *PureWick I* Judgment

The next factor in the collateral-estoppel analysis is whether the previous determination of invalidity was necessary to the judgment in the *PureWick I* case. *See Jean Alexander*, 458 F.3d at 249; *see also id.* at 250 ("Because litigants are likely to view an issue that is necessary to the resolution of a case as important and to litigate it vigorously, it is fair to give such a determination preclusive effect.").

a. Anticipation and Obviousness Defenses

Defendant does not address this factor as applied to its anticipation and obviousness defenses, instead focusing its arguments on the "identity of the issues" and "actually litigated" prongs of the collateral-estoppel analysis. (*See* D.I. 19 at 15-19). It would be hard for Defendant to contest that this factor is met. In *PureWick I*, the jury decided and the Court entered judgment of no anticipation and no obviousness of claims 1, 5 and 9 of the '376 Patent and claim 1 of the '989 Patent. (*See PureWick I*, D.I. 316 & 320). The Court upheld the jury's findings and also entered judgment of no anticipation of claim 6 of the '989 Patent. (*PureWick I*, D.I. 368 at 13-17, 40-42). The issues of anticipation and obviousness of the '376 and '989 Patents were actually litigated and necessary to the judgment in *PureWick I*.

b. Invalidity Defenses Under § 112

The Court has already found that the first and second prongs of the collateral-estoppel analysis are not met with respect to the § 112 invalidity defenses asserted in this case. (*See supra* § III.B.1.b & III.B.2.b). The Court again addresses this factor solely for the sake of completeness. Defendant argues that its § 112 invalidity defenses and counterclaims for the '376 and '989 Patents were not necessary to the resolution in *PureWick I*. (*See* D.I. 19 at 14). The Court agrees. For these two patents, only the issues of obviousness and anticipation were submitted to the jury and incorporated into the judgment in *PureWick I*. Invalidity under § 112 was not pursued at trial and not part of the verdict, any judgment or any court ruling. Therefore, the § 112 invalidity issues asserted here were not necessary to the decision in *PureWick I* and Defendant will not be precluded from asserting its invalidity defenses under § 112 for these patents in this litigation.

c. Unenforceability Defenses

On this factor as applied to the unenforceability defense of unclean hands, both sides make arguments that are difficult to follow. (*Compare D.I.* 13 (Plaintiff arguing that "resolution of

Sage's unenforceability counterclaims was necessary in *PureWick I* in order for the Court to enter judgment of infringement because an unenforceable patent cannot be infringed"), *with* D.I. 19 (Defendant arguing that "PureWick misunderstands the law . . . [and that] [d]etermination of one issue does not mean that another, unlitigated issue was 'necessary to the decision'")). But the Court has now granted Plaintiff's request for judgment on unclean hands in *PureWick I*. (*PureWick I*, D.I. 368 at 37-40). As such, the Court finds that unclean hands was necessary to the judgment in *PureWick I* and this factor is therefore satisfied.

4. Whether Defendant Was Fully Represented in *PureWick I*

The last factor evaluates whether Defendant was fully represented in previously litigating the invalidity issue sought to be precluded here. *See Jean Alexander*, 458 F.3d at 249; *see also Pharmacia*, 170 F.3d at 1379 ("[A] judgment of invalidity will have no collateral estoppel effect if the patentee can show that it did not have a full and fair opportunity to litigate." (citing *Blonder-Tongue Labs., Inc. v. Univ. of Illinois Found.*, 402 U.S. 313, 332 (1971))). The Supreme Court has articulated the relevant inquiry as one giving the patentee the ability to demonstrate that it "did not have a fair opportunity procedurally, substantively and evidentially to pursue [its] claim the first time." *Blonder-Tongue*, 402 U.S. at 333 (internal quotation marks and citation omitted). But as the Federal Circuit has cautioned, this factor is not focused on whether the prior invalidity determination was correct but rather on whether the patentee had a fair opportunity to litigate the issue. *See Stevenson v. Sears, Roebuck & Co.*, 713 F.2d 705, 709 (Fed. Cir. 1983) ("[I]t is clear from the case law that has developed since *Blonder-Tongue* that an inappropriate inquiry is

The Supreme Court provided some "relatively rare" scenarios where this may apply, such as when trial courts "wholly failed to grasp the technical subject matter and issues in suit" or when, through no fault of its own, the "patentee was deprived of crucial evidence or witnesses in the first litigation." *Blonder-Tongue*, 402 U.S. at 333.

whether the prior finding of invalidity was correct; instead, the court is only to decide whether the patentee had a full and fair opportunity to litigate the validity of [the] patent in the prior unsuccessful suit.").

Here, the Court will summarily address this factor as applied to the issues remaining eligible for collateral estoppel: anticipation, obviousness and unclean hands.¹³ Defendant has not demonstrated that it was deprived of a full and fair opportunity in *PureWick I* to litigate the validity or unenforceability of these patents. In fact, Defendant has not attempted to make such an argument. Indeed, it would be a hard sell as Defendant was represented by the same competent counsel in *PureWick I*. Thus, this last factor also supports application of collateral estoppel here.

5. Other Considerations

As set forth above, the four requirements of collateral estoppel are met and Defendant is estopped from asserting anticipation and obviousness invalidity defenses for the '376 and '989 Patents, and Defendant is also estopped from asserting its unenforceability defense based on unclean hands. Collateral estoppel does not apply and does not operate to preclude Defendant from asserting its § 112 invalidity defenses in this case.

Defendant asserts that "fairness" requires Defendant to be able to present its full complement of invalidity and unenforceability defenses because public policy favors "eliminating invalid patents." (D.I. 19 at 19). In support, Defendant argues that Plaintiff's "shifting positions" and trial-time limits in *PureWick I* prevented the ability to raise the defenses pursued here. (*Id.*). Yet the only shifting position that Defendant has ever identified is claim construction, which this Court has addressed. (D.I. 131). As to the time pressures of trial, the Court is unmoved. *See Strub*

The Court has already found that Defendant's § 112 invalidity defenses are not subject to collateral estoppel, failing the first three prongs of the test. (*See supra* §§ III.B.1.b & III.B.2.b & III.B.3.b). The Court has also declined to address inequitable conduct.

v. Axon Corp., 168 F.3d 1321, 1998 WL 537721, at *11 (Fed. Cir. 1998) (unpublished) ("It appears that Axon's decision not to pursue its counterclaim of invalidity was a strategic decision to concentrate what little time it had for trial on its case of noninfringement. We see no reason why Axon should be allowed to modify its litigation strategy in mid-course, forcing Marburg to expend time and money preparing for claims that were never litigated, only to withdraw those claims without prejudice when time pressures of trial dictated another course."). Defendant made strategic litigation decisions in PureWick I and, contrary to Defendant's assertion, it would be unfair to allow Defendant a second attempt on these issues when it already had the opportunity in PureWick I but chose a different path.

Defendant also argues that this case should be stayed pending resolution of the post-trial motions and any appeals in *PureWick I*. (D.I. 19 at 20). The post-trial motions in *PureWick I* have been resolved and a stay is therefore inappropriate on that basis. Additionally, the pendency or possibility of an upcoming appeal in *PureWick I* is likewise no basis for a stay here. Collateral estoppel applies regardless. *See DietGoal Innovations LLC v. Chipotle Mexican Grill, Inc.*, 70 F. Supp. 3d 808 (E.D. Tex. 2014) (Bryson, J. sitting by designation) (judgment of invalidity under § 101 from litigation in Southern District of New York applied in litigation in Eastern District of Texas despite likely appeal of the prior invalidity decision); *see also Pharmacia*, 170 F.3d at 1381 ("[T]he law is well settled that the pendency of an appeal has no effect on the finality or binding effect of a trial court's holding. (citations omitted)). It is a far more efficient use of time and resources to allow this case to proceed on the issues of infringement and invalidity under § 112. Thus, the Court declines to stay this case.

IV. CONCLUSION

For the foregoing reasons, Plaintiff's motion for judgment on the pleadings (D.I. 12) is GRANTED as to Defendant's anticipation and obviousness invalidity defenses and as to

Defendant's equitable defense of unclean hands, and DENIED as to Defendant's § 112 invalidity defenses. Defendant's request for a stay (D.I. 19) is DENIED. An appropriate order will follow.